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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,265	12/03/2001	Masatsugu Maeda	06501-096001 / C2-105DP1P	5055

26161 7590 12/13/2004

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EXAMINER	
RIGGINS, PATRICK S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,265	MAEDA ET AL.	
	Examiner	Art Unit	
	Patrick S. Riggins	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to nucleic acid, vectors, and transformants harboring the nucleic acids that encode NR10, classified in class 536, subclass 23.5.

II. Claims 9-10, drawn to purified NR10 protein, classified in class 530, subclass 350.

III. Claims 11-12, drawn to a method for producing NR10 protein, classified in class 435, subclass 69.1.

IV. Claims 13-14, drawn to screening methods using NR10, classified in class 435, subclass 7.1.

V. Claims 15-18, drawn to an antibody against NR10 and a detection method using this antibody, classified in class 530, subclass 387.1.

VI. Claim 19, drawn to nucleic acids that hybridize with NR10 sequences, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Group I is drawn to the nucleic acid encoding NR10 protein, whereas Group II is drawn to NR10 protein. Although it may appear that these groups possess a combination/ subcombination relationship, this is not the case. While the isolated nucleic acid of Group I can encode the protein of Group II, Group I is not a chemical constituent of Group II, thus these groups define distinct inventions. Additionally, the nucleic acid of Group I can be used in

processes distinct from the production of the protein of Group II such as in hybridization assays and the protein of Group II could be produced through materially different processes, such as biochemical purification from natural untransformed cellular lysates. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in materially different processes. The transformants of Group I that contain the nucleic acids of Group I are the product used in the process of Group II for making protein. Since the transformants of Group I, as claimed, would include such things as bacterial transformants and eukaryotic transformants, these transformants can be used for materially different processes than protein production such as studies to determine the activity of the NR10 receptors. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group I, restriction for examination purposes as indicated is proper.

4. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acids of Group I, though encoding the proteins used in the screening method of Group IV, can not themselves be used in these screening methods and are thus distinct. Because these

inventions are distinct for the reasons given above and the search required for Group I is not required for Group IV, restriction for examination purposes as indicated is proper.

5. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have no chemical or structural similarity and the nucleic acids of Group I cannot be used in the production methods of Group V. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group V, restriction for examination purposes as indicated is proper.

6. The inventions of Groups I and VI are distinct because the vast number of possible 15 mer polynucleotides of Group VI in itself presents a searching challenge and this burden would only be compounded by the additional search of Group I. Additionally, the inventions of groups I and VI differ widely in both their composition and their scope of potential uses, wherein the methods of their uses would be completely divergent. The nucleic acids of Group I, as claimed, are specifically required to encode protein whereas the polynucleotide of Group VI has numerous other uses aside from protein encoding. For example this polynucleotide could be used in hybridization screens such as Southern or Northern blots or for low stringency amplification methods to identify related genes rather than for the construction of NR10 protein. Indeed, it is highly unlikely that a 5 mer polypeptide encoded by a 15 mer polynucleotide of Group VI could retain the functional properties of a full-length receptor protein. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group VI, restriction for examination purposes as indicated is proper.

7. Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as biochemical purification of the protein directly from nontransformed cellular lysates. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because a search for art against Group II would not necessarily return art Group III, restriction for examination purposes as indicated is proper.

8. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed could be used in a materially different process such as the creation of antibodies such as those claimed in Group V. Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Group II, restriction for examination purposes as indicated is proper.

9. The NR10 protein of Group II, though the antigenic determinant for the antibodies of Group V, is chemically distinct from those antibodies and thus distinct. These groups are also distinct because the methods of Group V cannot use the proteins of Group II. Because these inventions are distinct for the reasons given above and the search required for Group V is not required for Group II, restriction for examination purposes as indicated is proper.

10. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are completely chemically distinct. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group VI, restriction for examination purposes as indicated is proper.

11. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods that have completely different steps and have wholly different products at the end of those steps. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper.

12. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Group V cannot be used in the process of Group III. Additionally, the process steps of the method in Group III are distinct from the process steps of the method in Group V and the products of the processes are completely distinct. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group V, restriction for examination purposes as indicated is proper.

13. Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are completely unrelated because the polynucleotides of Group VI cannot be used in the process of Group III. Additionally, the process of Group III produces a product distinct from the compounds of Group VI. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group VI, restriction for examination purposes as indicated is proper.

14. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups IV and V do not share any method steps and have completely different products from their processes and the antibodies of Group V can neither be used in the process of Group IV, nor are the process steps of Group IV. Because these inventions are distinct for the reasons given above and the search required for Group IV is not required for Group V, restriction for examination purposes as indicated is proper.

15. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Group VI cannot be used in the process of Group IV and the product of the process of Group IV is distinct from the compounds in Group VI. Because these inventions are

distinct for the reasons given above and the search required for Group IV is not required for Group VI, restriction for examination purposes as indicated is proper.

16. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Group VI cannot be used in the process of Group V and the product of the process of Group V is distinct from the compounds in Group VI. Because these inventions are distinct for the reasons given above and the search required for Group V is not required for Group VI, restriction for examination purposes as indicated is proper.

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick S. Riggins, Ph.D.
Examiner Art Unit 1636

JAMES KETTER
PRIMARY EXAMINER